

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ALNYLAM PHARMACEUTICALS, INC.,

Plaintiff,

v.

MODERNA, INC., MODERNATX, INC.,
and MODERNA US, INC.,

Defendants

C.A. No. 22-cv-335-CFC

JURY TRIAL DEMANDED

**MODERNA'S OPPOSITION TO NON-PARTIES ARBUTUS BIOPHARMA
CORP. AND GENEVANT SCIENCES GmbH'S MOTION FOR LEAVE TO
FILE AMICUS CURIAE BRIEF IN OPPOSITION TO MODERNA'S
PARTIAL MOTION TO DISMISS**

Dated: June 24, 2022

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I. INTRODUCTION

Arbutus and Genevant's motion for leave to file an amicus brief is an improper and untimely attempt to extend Plaintiff Alnylam's own opposition brief. The proposed brief is longer than Alnylam's brief, was noticed one business day before Moderna's reply, and consists largely of disputes that Alnylam chose to waive. It is an attempt to end run around this Court's briefing limitations and should be rejected. If it is not, then this Court may be faced with a series of related collateral filings tangential to the issues actually briefed between the parties.

II. FACTS

Arbutus and Genevant are currently engaged in a separate lawsuit against Moderna before Judge Mitchell S. Goldberg in this District. *Arbutus Biopharma Corporation et al v. Moderna, Inc.*, No. 22-cv-00252-MSG (D. Del. 2022). They allege, like Plaintiff Alnylam in this case, that Moderna's COVID-19 vaccine Spikevax® infringes certain of their patents. In both that lawsuit and this one, Moderna moved for partial dismissal under 28 U.S.C. § 1498, arguing that sales to the U.S. Government were immune from suit. The two sets of Plaintiffs, relying on two distinct complaints, opposed Moderna's motion in different ways. *Compare* D.I. 14 (Alnylam) *with* D.I. 16-2 (Arbutus and Genevant). Alnylam opposed Moderna's motion on procedural grounds, arguing that application of § 1498 was premature at the 12(b)(6) stage (D.I. 14 at 7–8), that Moderna's government contract

was not judicially noticeable (D.I. 14 at 9) and that, in the alternative, the scope of acts covered by § 1498 was not determinable at the 12(b)(6) stage (D.I. 14 at 10–14). Meanwhile, Genevant and Arbutus primarily disputed the applicability of § 1498, arguing for a different legal interpretation of its scope (D.I. 16-2 at 9–12), and for its factual inapplicability to Moderna’s conduct based on the particular facts alleged in that case (D.I. 16-2 at 12–20).

Now, Alnylam, Arbutus, and Genevant seek to introduce Arbutus and Genevant’s opposition brief from their case as an amicus brief in this case. If permitted to do so, they would effectively double Alnylam’s page limit and give it a belated second bite at the apple, raising an entirely new set of merits disputes at the close of the briefing cycle. At this stage, the additional briefing is irrelevant and improper. It fails to address the disputes actually before the Court and, furthermore, is overly long and untimely. Granting leave here would only burden the Court with an incomplete account of the disputes in the Arbutus and Genevant case and set a precedent for regular cross-filing of briefs, potentially doubling the papers for the life of this litigation and creating undue risk of collateral conflict with Judge Goldberg.

The Court should exercise its discretion to deny Arbutus and Genevant’s motion for leave or, in the alternative, grant Moderna leave to file a reply.

III. ARGUMENT

A. Legal Standard

In the Third Circuit, “a district court’s decision to accept or reject an amicus filing is entirely within the court’s discretion.” *Wortham v. KarstadtQuelle AG*, 153 F. App’x 819, 827 (3d Cir. 2005). District courts’ discretion is “guided by the Third Circuit’s application of Federal Rule of Appellate Procedure 29.” *Granillo v. FCA US LLC*, No. CV16153FLWDEA, 2018 WL 4676057, *4 (D. N.J. Sept. 28, 2018). Thus, courts consider factors such as “whether (1) the amicus curiae has a ‘special interest’ in the particular case; (2) the amicus curiae’s interest is not represented competently or at all in the case; (3) the proffered information is timely and useful; and (4) the petitioner is not partial to a particular outcome in the case,” *id.*, or whether “(1) the movant has an adequate interest in the appeal; (2) the information supplied is desirable; and (3) the information being provided is relevant,” *In re Weinstein Co. Holdings, LLC*, No. BR 18-10601-MFW, 2020 WL 1320821, *1 n.3 (D. Del. Mar. 20, 2020), *aff’d sub nom. In re Weinstein Co. Holdings LLC*, 997 F.3d 497 (3d Cir. 2021).

For example, leave may be denied when “amicus briefs ... make an end run around court-imposed limitations on the length of parties’ briefs,” especially when doing so creates “extraneous reading” that exacerbates judges’ “heavy caseloads” and “drive[s] up the cost of litigation.” *Voices for Choices v. Illinois Bell Telephone*

Co., 339 F.3d 542, 544 (7th Cir. 2003). In general, amicus briefs “[a]t the trial level ... may be less appropriate than at the appellate level” because issues of particular fact predominate over issues of law or policy. *Yip v. Pagano*, 606 F.Supp. 1566, 1568 (D. N.J. 1985). Thus, even under “the most lenient standard,” “[c]ourts will deny leave in instances where the arguments and facts in the brief are patently partisan, are untimely, and where the litigant is competently and adequately represented.” *In re Weinstein Co. Holdings, LLC*, 2020 WL 1320821, *1 n.3.

B. The Proposed Amicus Brief Is an Improper and Untimely Extension of Plaintiff’s Opposition Brief

The proposed amicus brief here does not provide useful, relevant, or desirable information. The majority of Arbutus and Genevant’s brief is devoted to legal and factual disputes that Alnylam has not raised and thus has waived. Alnylam chose not to argue that § 1498 does not apply as a matter of law (*see* D.I. 16-2 at 9–12), or that the complaint plausibly alleges facts vitiating its applicability (*see* D.I. 16-2 at 12–17). Arbutus and Genevant’s main arguments are irrelevant to the particular disputes in this case—not least because this case is governed by a different complaint. Their brief does not elucidate the parties’ positions in this case, or the legal or policy consequences thereof; it merely introduces a new, alternative set of substantive oppositions to Moderna’s motion.

To the extent the new arguments might be relevant, they improperly introduce novel substantive disputes extending beyond Alnylam’s page limits and briefing

deadlines. The proposed amicus brief is longer than Alnylam's own brief by five pages, and in smaller font than permitted by this Court's rules. *Cf.* F.R.A.P. 29(a)(5) (requiring amicus briefs to be no longer than half as long as a principal brief). Further, the brief was noticed more than two weeks after Alnylam filed its opposition, only one business day before the close of briefing. *Cf.* F.R.A.P. 29(a)(6) (requiring amicus briefs to be submitted no later than 7 days into the 30 days available for an appellant's reply). If leave were granted under these circumstances, Moderna would have no opportunity as of right to respond to the new disputes, and the Court would be hindered from gathering complete and balanced arguments. *Cf. Dobson Mills Apartments, L.P. v. City of Philadelphia*, No. 21-CV-273, 2022 WL 558348, *2 (E.D. Pa. Feb. 23, 2022) (denying amicus motion noticed too late after original brief).

While a briefing imbalance could be cured by granting Moderna leave to file an additional reply, that would set a precedent for Moderna and proposed amici to cross-file briefing from their parallel litigation whenever there is a potential issue overlap with this case. The Court would be faced with additional rounds of papers at potentially every stage of this litigation, and would be left to infer which part of the excess papers were applicable to this case and which part applied only to the factual context of the other case. Indeed, where amicus briefing is normally valued for improving the Court's understanding of the dispute before it, the proposed brief

would accomplish the opposite: introducing extraneous disputes and papers that necessarily lack context and needlessly increase the Court’s burden.

Finally, because the issues raised in the proposed brief will already be decided by Judge Goldberg, admitting the brief here would waste judicial resources and invite improper collateral conflict. As stated in *Dow Chem. Co. v. United States*, No. 00-CV-10331-BC, 2002 WL 33012185, *2 (E.D. Mich. May 24, 2002), a “[proposed amicus] ought not to be permitted to [l]itigate its own lawsuit under the guise of [an amicus brief] ... It is not the proper office of an *amicus* brief, whose primary purpose is to assist the Court in reaching a decision, to collaterally attack [a parallel litigation].” Such a “proposed filing will not aid the Court in resolving the issues before it, there is no need to supplant the development of the issues already explicated by the parties to this case, and it is not desirable to add to the already voluminous record before the Court.” *Id.* There is simply no reason for this brief to be filed in this case.

C. The Proposed Amici Are Partisan to Plaintiff and Have No Interest That Is Not Competently Represented by Plaintiff

The remaining factors also weigh against granting leave in this case. Arbutus and Genevant are not merely interested in this case, but heavily biased against Moderna, and against Moderna’s § 1498 motion in particular. They are “better characterized as ‘amicus [petitor]’ or friend of the [Plaintiff], than amicus curiae.” *Sciotto v. Marple Newtown Sch. Dist.*, 70 F. Supp. 2d 553, 556 (E.D. Pa. 1999). “[A]

memorandum amicus petitor, one proffered as a friend of the plaintiff(s) ... is not proper in a trial court ... because it injects an element of unfairness into the proceedings[.]” *Leigh v. Engle*, 535 F.Supp. 418, 422 (N.D. Ill. 1982). Because of their close alignment with Alnylam, proposed amici also raise no interest that is not already competently represented—no unique or new perspective. They merely duplicate Plaintiff’s interest with an alternative host of legal and factual arguments.

IV. CONCLUSION

For the foregoing reasons, Moderna respectfully requests that the Court deny Arbutus and Genevant’s motion for leave to file their improper amicus curiae brief. In the alternative, Moderna respectfully requests that it be granted leave to file a reply in the form of its reply to Arbutus’s brief from the case before Judge Goldberg.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the length, type, and font limitations set forth in Judge Connolly's Standing Order Regarding Briefing in All Cases (Nov. 6, 2019) because it is prepared in 14-point Times New Roman typeface and contains 1,628 words out of a permitted 5,000, as determined by the word count function of the word-processing program used to prepare this filing, excluding the parts of the brief exempted by Delaware Local Rule 7.1.3.

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